REMARKS

At the outset, Applicants appreciate the Examiner's care and considered review of their application as reflected in the Office Action.

Applicants have endeavored to respond to the Office Action and respectfully suggest that upon reconsideration, their application will be found in condition for allowance.

Claim Amendments

Amended claim 17 finds basis in the specification. The Examiner will appreciate the difference between the additional free amino acids from minor amounts that might be present if a protein hydrolysate were present. The specification in Table 1, third study, discusses these differences and includes evidence demonstrating differences in results.

Amended claim 33 corrects the dependency. Applicants acknowledge the Examiner's courtesy in calling this matter to their attention.

Comments re: April 23, 2001 IDS

Upon reviewing the file, it was noted the Examiner crossed out citations for FR 2710244 and EP 418593 in the PTO 1449 form (see Applicants' IDS dated April 23, 2001, disclosing a foreign search report with Annex along with each of the cited references). English language abstracts to the FR 2710244 and EP 419593 references are attached. The abstracts were obtained from an internet site that is also accessible to the Examiner. Applicants respectfully request the Examiner to acknowledge the references and their consideration in the next official communication.

Traversing the Rejections

The Examiner rejected claims 17-22, 24-33, and 35-41 under 35 U.S.C. §103(a) over the Kahn reference, EP 0421309A2. The Examiner rejected claims 17-41 under 35 U.S.C. §103(a) over the Kahn reference, EP 0421309A2 in view of the Kingham reference (WO 95 22909). Applicants respectfully traverse these rejections and request their reconsideration and withdrawal.

Applicants' claims 17-22, 24-33, and 35-41 define novel and unobvious inventions over the Kahn et al. reference. The Kahn reference does not disclose, suggest or teach an

combining additional of free leucine and/or phenylalanine with a composition (hydrolysate or other composition). Applicants therefore respectfully suggest that the Office Action at page 4, lines 9-10 errs in its extrapolation from the abstract to the Kahn reference. Contrary to the Office Action, *arguendo*, even if the Kahn reference did disclose a protein hydrolysate (which might have some free amino acids or in peptide form - page 4, line 8, page 5, line 14), the reference still neither discloses nor would it have taught including additional amount(s) of each of the free amino acids.

The reference implies that free amino acids may or may not be present in a hydrolysate as suggested by page 5, lines 18-19. However, in context the disclosure concerns the whey/soy/casein protein hydrolysate at page 5, line 14. Still further, the other passages in the Kahn reference exemplifying compositions, such as at page 8, lines 30-51, page 10, lines 19-40, page 12, lines 20-42, page 14, lines 26-47, page 15, lines 43-56, page 17, lines 20-42, page 18, lines 12-29, all concern overall composition of a hydrolysate, but do not specify levels of each individual free amino acid. It is not seen where the reference would have motivated an ordinary person to leucine and phenylalanine.

Moreover, the Kahn reference is silent as to any individual levels of leucine and phenylalanine in a hydrolysate, and has no teaching to add additional amounts of leucine or phenylalanine to a hydrolysate.

Applicants appreciate the Office Action at page 8 alleges that the Kahn refernce mentions free amino acids, citing the reference at page 8, lines 3-50 (Example 5). This characterization of the Kahn reference, even if true, would not have suggested, motivated, taught or led a person of ordinary skill in the art to add an amount of an additional free amino acid to the protein hydrolysate of the reference, as seen from the following.

Applicants respectfully direct attention to Examples 1-24 in the Kahn reference because none of such Examples disclose or suggest an additional amount of leucine and phenylalanine. A quick run through of illustrative Examples from the Kahn reference demonstrates this point.Example 1 merely discloses pasteurization of a soya selected whey protein mixture. Example 2 discloses preparation of a selected whey protein. Example 3 concerns pepsin hydrolysis of the soya selected whey protein mixture, but offers no suggestion of adding any amount of additional free amino acid to the mixture. Example 4 discloses a hydrolysate but nothing about additional amounts of any free amino acid.

Example 5 discloses a hydrolysate concentrate, a flash treatment, pasteurizing a reaction mixture, using ultrafiltration, diafiltration of a retentate, cooling the permeate, concentrating the concentrate, and spray drying., but Example 5 discloses nothing about additional amounts of any free amino acid. Example 6 discloses pepsin pre-hydrolysis but nothing about adding any amounts of any free amino acid to the concentrate. Examples 7-8 concern a rennet casein hydrolysate but nothing about adding any amounts of any free amino acid to the hydrolysate. Examples 9-12 apparently pertain to whey protein and whey protein hydrolysate concentrate (Example 12), but none suggest additional amounts of any free amino acid. Example 17 concerns a soya/selected whey protein hydrolysate concentrate, but provides no teaching to add any free amino acid to the concentrate. Examples 19-21 concern a rennet casein hydrolysate but none provide suggestion of adding any additional amount of any free amino acid to the hydrolysate. Example 22 includes tabluated information about typical amino acid concentrations of hydrolysates according to the Kahn et al. invention, but nowhere does it teach adding any amount of any additional free amino acid to any hydrolysate. The formulations according to Example 23 likewise fail to suggest adding any amount of any additional free amino acid to a hydrolysate or to any other composition.

Furthermore, Table 1 illustrates the effects that can be achieved by the present invention. The third reported study shows that beneficial effects attained by a protein hydrolysate plus the addition of specified amino acids (not the hydrolysate) versus the results if one used only a hydrolysate without further addition of the amino acids. The former illustrates the present invention and the latter may be said to be indicative of an approach per the Kahn reference. The Examiner's attention is respectfully invited to page 9, line 18 *et seq.* wherein it is reported that healthy trained athletes - after physical exercise - were tested with drinks 11-15. The results in Table 1 show drinks 14 and 15 produced a much higher insulin response than drinks 11-13. This may be further considered by comparing results with drink 12 with drink 14; and drink 13 with drink 15. It will be further understood that doubling the amount in drink 14 further increased the induced insulin response (drink 15), which was not the case with going from drink 12 to drink 13. Thus, the evidence of record shows that products according to the claimed inventions provide enhanced insulinotropic effect after or during physical exercise, which are not disclosed or suggested by the Kahn reference.

Lastly, Applicants respectfully point out that the statute, 35 U.S.C. §103(a), specifically directs patentability shall not be negatived by the manner in which the invention was made. This statutory mandate means assertions of 'routine experimentation' or 'routine optimization' are proscribed as bases for rejecting claims. *See, e.g.*, In re Fay, 146 USPQ 47 (CCPA 1965) (reversing obviousness rejection based on allege routine experimentation)

Applicants claims 17-41 define novel and unobvious inventions over the Kahn et al. reference in view of the Kingham reference.

The above-discussed shortcomings in the Kahn reference would not have been remedied even if a person of ordinary skill in the art combined the Kahn reference with the Kingham reference.

The Kingham reference concerns protein management for Parkinson's Disease for which the group of large neutral amino acids (LNAA type therapeutic agents) has relevance as they may cross the blood brain barrier. with this in mind, it is evident that the reference teaches formulating two groups of different amino acids. For ease of reference, in the published claim 1 the weight to weight ratio of the two groups of amino acids varies from about 3:1 to 6.5:1. The weight ratio according to the Kingham reference is actually contradictory to Applicants' specification, Table 1, whereby even if the Kingham reference alludes to adding unspecified amino acids, Office Action at page 8, the hypothetical addition would be to satisfy those contradictory ratios. Applicants's Table 1 shows drink 6 with 1.90 arginine versus 1.90 l;eucine and 1.90 phenylalanine; drink 7 with 1.43 arginine and 1.43 glutamine verus 1.43 leucine and 1.43 phenylalinine; and drink 9 with 0.95 arginine versus 0.95 leucine and 0.95 phenylalanine to illustrate the advantages of the present invention, which include enhanced recovery after physical exercise. In short, the evidence shows that Kingham is contrary to the present claimed invention which contemplates a composition having an additional free amount of leucine and or phenylalanine to obtain the insulin response needed to stimulate glycogen resynthesis following intense exercise. Therefore, the present recited claims define unobvious inventions even if the Kahn reference were combined with the Kingham reference.

Method claims 39 and 40 find no touchstone in the applied references. An insulin response upon consumption of a carbohydrate drink could be elicited when phenylalanine and leucine were added to the composition. In fact, the insulin response was linear with the

phenylalanine and leucine intake (Table 1, 3rd study of the present application). This discovery was very surprising and unexpected, and it not seen where such composition or the results obtained therefrom would have been foreseen from the Kahn reference or from the Kingham reference since neither is concerned with enhancing recovery after or during physical exercise.

Accordingly, Applicants submit that their claims define over the references, even if they were combined.

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue.

If any questions remain, please contact the undersigned to arrange for a telephone or personal interview with the undersigned attorney for Applicants.

Respectfully submitted,

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APPENDIX

Amended claims:

17. (Amended) A composition comprising carbohydrate and peptide material; and, in addition, two free amino acids consisting of leucine and phenylalanine, wherein each [said] free additional amino acid is present in an amount in the range of 0.2 to 20 weight percent, calculated on dry matter basis**; and wherein each said additional amino acid is distinct from any free amino acid that may be present from the peptide material**.

33. (Amended) The composition according to claim **17** [1], wherein said composition further comprises at least one member selected from the group consisting of a vitamin, a flavor, a mineral, a lipid, and a protein.